Risk Assessment: The Perspective and Experience of U.S. Environmentalists

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Risk assessment is a set of decision rules widely used in the United States for identifying and quantifying the risks of chemicals and other events for adverse effects to human health, usually cancer. Scientific criticism has been directed toward the default assumptions and test methods used in risk assessment by regulatory agencies. This paper evaluates the contribution of risk assessment as an instrument of public policy toward the timely and efficient resolution of controversial issues in environmental and occupational health. Experience with risk assessment during the past decade does not support its utility in this regard. Alternatives to risk assessment in its current formulation are discussed. **Key words:** aryl hydrocarbon receptor, carcinogen identification, Environmental Protection Agency, risk assessment, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin. *Environ Health Perspect* 101:100–104(1993)

Since 1981, risk assessment has formed the methodological basis for much public policy related to the regulation of occupational and environmental chemicals in the United States. The adoption of risk assessment as a policy instrument to identify and quantify risks of cancer associated with chemical exposure was largely due to public concern about the potential contribution of chemical exposures to cancer (*1*) and political frustration with delays in action by the EPA and the Occupational Safety and Health Administration (OSHA). In addition, pressures from industry (often exerted through litigation) required EPA and OSHA to provide a scientific rationale for specific regulatory decisions (*2*).

There have been many scientific critiques of risk assessment, in theory and in practice. Here I consider the pragmatic value of risk assessment as a method for reaching public policy decisions from the perspective of an environmentalist. My criteria are primarily operational, rather than theoretical: What has been the contribution of risk assessment, in practice, to the efficiency, adequacy, clarity, enforceability, and public acceptability of government regulation since 1981?

Early History of Risk Assessment. In 1979, an interagency committee of the U.S. government proposed guidelines for identifying and assessing chemical carcinogens [see *Identifying and Regulating Carcinogens* (*3*) for a history of carcinogen policy in the United States]. These guidelines have been the source of subsequent science policy for occupational and environmental regulation since that time. Before 1979, regulation of toxic chemicals had generally been based on one of three principles: technology-based control, risk–benefit balancing, or banning. The technological basis for regulation was predicated on the availability of control technology (*4*) or on the limits of analytical chemistry (*5*). However, policy based on these concepts is inherently unsatisfactory because it limits risk reduction to those actions achievable through currently available technology (although specific statutory language can and has been used to elicit advances in technology). Further actions may be precluded in those cases where high levels of pollution remain even after maximally achievable controls are imposed or where analytical chemistry is not sensitive enough to measure contamination at the point of release. This latter concern is particularly relevant to regulating persistent, bioaccumulated chemicals discharged into surface waters because measurement at the point of discharge may not adequately prevent long-term accumulation, as in the case of organochlorine contamination of the Great Lakes (*6*).

The risk–benefit balancing approach to regulation, embodied in the U.S. statutes regulating pesticides, incorporates an assumption that such a balance can be found (*2,7*). In other words, the balance assumes that there are levels of exposure where risks are very low or nonexistent such that the net benefits of continued use are clear. In the early 1970s it was generally assumed that some pesticides were nontoxic to nontarget species at some dose, either because of the nature of their toxic effects ("threshold effects") or because of qualitative differences in species response ("selective toxicity") (*8*).

The third approach, banning, was included by Congress in those statutes that empowered or obligated regulators to use the option to ban production or use of a chemical entirely, based solely on finding it was hazardous (*2*). The Delaney amendments to the Food, Drug, and Cosmetic Act, sections of the Clean Air Act, and the Federal Insecticide, Fungicide, and Rodenticide Act permitted agencies to prohibit releases and uses of substances identified as carcinogens without the need to calculate the *extent* of the hazard, which is the function of risk assessment.

Risk Assessment through the 1980s. The convergence of new statutes, new public health concerns, and new developments in science caused many environmentalists and others to reconsider the appropriateness of these approaches to regulating all types of toxic chemicals (*9*). The new statutes, such as the Toxic Substances Control Act, required more explicit risk balancing. New initiatives by EPA and OSHA to regulate a broader range of industrial chemicals provoked strong response from the regulated community. Scientific developments suggested that rapid test methods geared toward identifying mutagenic properties of chemicals could be useful in speeding up regulatory review. Public concern about cancer was heightened by President Nixon's declaration of a "war on cancer" in 1971, which coincided with the creation of EPA and OSHA. One element of the war on cancer was disease prevention. After considerable controversy, the public health community had succeeded in translating the scientific consensus on the carcinogenic effects of cigarette smoking (*10*) into public policy. The search for other opportunities to prevent cancer by controlling identifiable chemical etiologies was advanced by the development of simple assays for mutagenesis, which was thought to be a characteristic property of chemical carcinogens.

Prevention, as part of public health policy, assumes the obligation to act before the induction of disease or death. To completely prevent chemical-induced disease, it is necessary to act before information on human response is complete. The 1979 proposals on risk assessment, restated several times in the 1980s, were premised on the following principles: chemical exposures are a significant contribution to the overall incidence of human cancer; chemical-induced cancers can be prevent-

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ed by identifying potential human carcinogens before human exposure on such a scale that epidemiological studies can demonstrate plausible associations between exposure and disease; and the evaluation of potential carcinogens should be quantitative as well as qualitative in order to ensure that regulations meet the criteria of the risk-balancing statutes (*3*).

Debate continues over the quantitative contribution of chemical exposures to human cancer (*10–13*). It is unlikely that epidemiological studies can completely resolve this issue, given problems in exposure assessment and the likelihood of complex interactions among chemical exposures, genetics, and lifestyle factors (including smoking and diet).

Methods for identifying carcinogenic chemicals have been applied for more than a decade, using animal models, structure–activity analyses, and short-term *in vitro* tests (*13,14*). But as data were acquired from these procedures, regulatory agencies needed criteria to judge the results of these tests and assays, examples of which can be found in the decision rules of the U.S. National Toxicology Program (NTP) and the International Agency for Research on Cancer (*14*). Moreover, for regulatory purposes, qualitative methods were insufficient to support regulation, particularly after the U.S. Supreme Court struck down OSHA's benzene standard in 1980 because of the insufficiency of a science-based rationale for risk assessment and reduction.

From 1979 to 1987, U.S. regulatory agencies developed more specific principles on which to base quantitative risk assessment for chemical carcinogens and other agents. These principles were bounded by several important policy decisions that were generally accepted, although not without controversy: First, risk assessment was to proceed in the absence of data on human response, relying when necessary on results from experimental research; second, agencies were to provide quantitative estimates of dose at a level of risk that was deemed to be politically acceptable; and third, risk assessments were to be presumptively conservative, that is, protective of human health in the case of uncertainty. These are policy decisions that have largely shaped the continuing debate over risk assessment in the United States (*15–17*).

Acceptability of Risk Assessment in Theory and Practice. Although risk assessment has been central to U.S. policy making since 1980, the environmental community remains divided on its acceptability as a policy tool. For some, the mere use of risk assessment is an admission that a certain amount of risk is acceptable; to these and other advocates, the imposition of any risk is unlawful under certain statutes (such as the original Clean Air Act and the Delaney Clause) and unethical in most circumstances (*16,17*). This is a powerful argument, and the American tradition of rejecting unequal treatment under the law challenges the allocation of individual risks in a way that inevitably affects some person(s) more than others (and others not at all, given the strict interpretation of risk assessment as a probability estimate). When a pattern appears to occur in which risks are often borne by one group whose members generally have less access to economic and political power, broad issues of civil rights have been raised by the environmental justice movement (*18*).

Other environmentalists have supported the appropriate use of risk assessment because of its potential to increase the speed and resource conservation of government response in preventing disease. These environmentalists have generally supported a strict interpretation of risk assessment guidelines at the level of hazard identification (that is, the criteria that support the designation of a chemical as carcinogenic in humans based on animal data) and have resisted modifications in the methods of dose–response calculation and dose–exposure extrapolation (*19*). These proponents have argued for continuing the qualitative assumption that animal carcinogens, under any circumstance of dosing including the maximally tolerated dose, are probably human carcinogens.

The most controversial provisions of current methods of quantitative risk assessment are the default assumptions for quantifying exposure and risk at very low levels, in the range generally considered acceptable by policymakers (that is, between 1:100,000 and 1:1,000,000). The major default assumption is based on a single-hit theory of genotoxicity as the basis for the linearized multistage model of carcinogenesis, which provides the rationale for the statistical approaches used to derive unit risk estimates from experimental dose–response data (*14*). Because policy decisions require estimation of dose beyond the range of feasibly obtainable experimental or human data, inference rules must be used to extrapolate to the range of concern. Since 1980 EPA has relied on the assumption that chemical carcinogens at small doses nevertheless increase the probability of cancer by some amount greater than zero, and that in the low-dose range, increments of dose are associated with proportional increases in risk (*3,9*). This assumption, being generic, does not necessarily reflect chemical-specific mechanisms of action.

The default assumptions and the rules that cover low-dose extrapolation have been defended on the grounds that they provide conservative buffers for uncertainty and possible variations in sensitivity within the human population (*11,14, 19,20*). Critics, particularly those who favor less stringent or less frequent regulation, have objected to the bias toward conservatism in risk assessments (*21,22*); however, as pointed out by Finkel (*23*), it is not clear that these biases always result in gross overestimates of risk (*20,24*). Others have challenged the relevance of animal data for particular types of carcinogens on the basis of purported species differences in metabolism, target tissue response, or inherent sensitivity differences among species (*25–27*). In particular, some critics have argued that physiologically based pharmacokinetic information should be considered in the process of developing risk assessments in extrapolating from test species to predicted human exposures and adverse effects (*13,28*). However, the acquisition of agent-specific pharmacokinetic information adds greatly to the burden of gathering data for regulatory purposes. There is likely to be considerable variation within the human population with respect to pharmacokinetics, depending on genetics, age, and diet, as well as possible pharmacokinetic interactions among toxic chemicals and other substances, so that improving the precision of our knowledge of inbred rodents may not improve the predictability of risk assessments for public health purposes. The expansion of the time and resources needed to carry out risk assessments may be scientifically attractive, but it has major impacts on the allocation of resources in government and the private sector (*29*), and, as argued by Lave et al. (*30*), it may not be cost effective as an investment for decision making.

Over the past 10 years, these objections have been raised in the context of proposals to regulate specific chemicals such as methylene chloride, formaldehyde, perchloroethylene, and the dioxins. In no instance have the critics presented compelling scientific evidence to justify alternative approaches to risk assessment, except for the generic call for "more (or better) science." A recent consideration of one of the most controversial issues in risk assessment, the use of the maximally tolerated dose in carcinogen bioassay tests, could not be resolved by a panel of experts recently convened by the National Research Council (*31*).

In principle it is unreasonable to object to the admission of "more (or better) science" in risk assessment. Relevant data on specific chemicals may be very useful in judging the applicability of the general default rules, as well as in more precisely

estimating risk using the linearized multistage model. The problem is that we do not really know what these data are or how we would incorporate them into alternative methods of risk assessment. Some critics of risk assessment disagree with the process of hazard identification, and they do not accept the NTP bioassay as a reliable method of identifying carcinogens (*26,27*). It is not always recognized that risk assessment is primarily a policy tool (*20,29*) and not the optimal method of testing scientific hypotheses. Public health policy and clinical medicine have similar relationships to basic science: both are practical disciplines that demand, at some point, action even in the face of residual uncertainties.

Costs and Benefits of Risk Assessment. Has the use of risk assessment improved policy making, in terms of efficiency (use of government and nongovernment resources), speed, and public acceptability? The record over the past decade does not support a positive answer, although it is difficult to distinguish problems in the process from those of political interference (*15,32*). Despite the confidence of some that risk assessment could be insulated from the political and economic parts of policy making (*9,33*), it is in practice usually impossible to separate risk assessment and risk management from each other (*15*).

It would be difficult to claim from the record that the U.S. process of policy making with regard to regulating chemicals is efficient in terms of resource demands or expeditious in terms of time to closure. One problem with the adoption of risk assessment as a policy tool is the difficulty in terminating data accumulation, even temporarily. Even if research continues, it is unlikely to reach incontrovertible uncertainty. Risk assessment per se provides no guidance as to how much information is sufficient for decision making (*2*). For most of the chemicals of public concern in the 1980s (lead, dioxin, formaldehyde, ethylene dibromide, benzene), no final regulatory action has resulted even after years of arguments over data and data analysis.

Risk assessment can encourage the use of research as a delaying tactic, given the high stakes of most regulatory action in the United States. Because it is impossible for EPA to issue interim rules for a particular chemical, each step in the process has increasingly higher stakes for all parties concerned. The history of EPA's dealings with the dioxins is illustrative (*6*). By the end of the 1970s, EPA had concluded its first evaluation of the health and ecological hazards of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) in connection with regulations under the Clean Water Act. However, in 1981, after intervention by the Dow Chemical Company, no regulations were issued. In 1983, the second wave of environmental controversies over dioxin erupted, with the discovery of contamination in communities in Missouri, Illinois, and New York. The strong provisions of the hazardous waste cleanup statute, CERCLA or Superfund, required EPA to take action at these sites, but it did not mandate a standard for cleanup in this case or elsewhere. The agency's hand was forced by the Centers for Disease Control, whose scientists used risk assessment principles to calculate public health guidance for evacuation of contaminated communities in Missouri.

EPA reopened its risk assessment for the dioxins shortly afterward, and in 1986 the first health assessment document for TCDD was published. Using standard methods of quantitative risk assessment, the EPA proposed a very low unit risk for lifetime exposure to TCDD, 0.016 fg/kg/day (a unit risk is the lifetime daily dose associated with an increase in cancer risk of 1:1,000,000). This risk assessment raised political controversies as more and more dioxin-contaminated sites were discovered. In addition, it was found that municipal waste incinerators could be sources of dioxins from the incomplete combustion of certain precursor materials in the presence of halogens (*34*). The Environmental Defense Fund (EDF) petitioned and later sued the EPA under the Toxic Substances Control Act to regulate the ongoing releases of dioxins and related compounds from a range of sources, including chemical production, industrial waste disposal, and solid waste incineration. An important part of EDF's petition was the novel proposal to treat the dioxins (and furans) as a class of similarly toxic chemicals, based on structural fit to the dioxin or Ah receptor. This proposal has now been adopted by EPA and many national regulatory agencies in the toxic equivalency factor approach (*6*).

The recognition that municipal incinerators were important sources of dioxins was politically controversial, and regulation was delayed as EPA undertook another risk assessment in 1988. EPA's first proposal was to average the risk estimates produced by its scientists, those at CDC, and at other national agencies, but objections to this method encouraged EPA to adopt a more science-based approach (*6,35*). The conclusions of that review were basically a restatement of the 1986 risk assessment.

However, a new political obstacle to regulating dioxins arose with the revelation from EPA's National Dioxin Survey that pulp and paper mills could also generate substantial amounts of dioxins and furans through the use of chlorine bleaching. The paper industry, facing strict controls on its discharges and waste disposal practices (including bans on burning and land farming of solid wastes), forced EPA into reconsidering the TCDD risk assessment. The third risk assessment is ongoing at EPA (as of April 1993). Enormous pressure has been brought on regulators and scientists involved in reassessment (*6*). The chlorine industry contributed funds for convening a scientific meeting at the world-renowned Banbury Center in October 1990; a public relations firm retained by the industry then disseminated misleading information on the nature and conclusions of this meeting (*6*).

This process of assessment and reassessment has not encouraged public confidence in risk assessment (*16,17*). Moreover, the highly sophisticated use of risk assessment methodologies by the waste management industry, seeking permits to site incinerators and landfills, has increased public suspicion of the validity of the numbers because of the apparent ease with which consulting risk assessors can produce large numbers of documents purporting to estimate the precise risks of such facilities.

Public suspicion of risk assessment has been attributed to public ignorance of the nature of risk and the technical steps of risk assessment (*22,36,37*). If ignorance is the source of the public's reaction, then it is important to consider how, and whether, it can be overcome. A decision-making process that is inaccessible to public understanding is contrary to the principles of American government (*33*). On the other hand, the public may not be ignorant but rather cannily skeptical of a method that does not seem able to generate stable estimates of risk. Unless the method can be greatly im-proved and a broader consensus generated as to its acceptability and its scientific validity, it will not be possible to persuade the public to believe in something that industry, environmentalists, and academic scientists periodically attack in both theory and practice.

Alternatives to Risk Assessment. Risk assessment, as noted above, arose from scientific advances in the identification of chemical carcinogens, pressure on agencies to specify risks more precisely and with more documentation, and the desire of the public for more regulation of toxic chemicals. However, the practical use of risk assessment in public policy does not seem to have answered these needs. Risk estimates may appear to be more precise than general statements of hazard, but few groups (industry, regulators, scientists, or the public) have faith in their precision. Scientific advances in our knowledge of carcinogenesis make the process more complicated and open up more possible

models to guide low-dose and species-to-species extrapolation (*31*). The last decade has seen fewer regulations, rather than more, compared with the 1970s.

There are alternatives to risk assessment. First, we could return to the technology-based approach or we could extend the obligation to ban. Both of these approaches, as discussed above, are based on the qualitative finding of risk (hazard identification), which triggers either the application of best available control technology or an outright ban or restriction on use. Commoner (*16*) has argued that only bans have significantly reduced environmental risks, citing the consequences of EPA actions to ban DDT and polychlorinated biphenyls and the success in lowering human lead exposure in the United States after drastic reductions in the allowable levels of lead in gasoline. International agreements to ban the production and use of ozone-depleting chemicals are more recent examples of this approach (*38*), as is the Organization for Economic Cooperation and Development experiment in multinational approaches to risk reduction for "sunset" chemicals, whose risks are considered sufficiently great that no quantitative calculation of risk is necessary to justify concerted action.

Second, we could adopt simpler rules to estimate risk. The European approach, applying a safety or uncertainty factor to all types of toxicants, avoids the need to select mechanism-based approaches to classes of toxicants based on an endpoint and an assumed mechanism of action. An advantage of this approach is that it restores priority for chemicals that may not be carcinogenic but that are highly toxic to the reproductive or nervous systems. Arguably, these types of chemical risks have been overlooked in the United States in the past decade (*39*). However, this approach does not reduce the problems of determining levels (no effect or lowest observed effect) to which to apply safety or uncertainty factors (*40*).

Third, we could use novel tools of risk reduction that avoid or reduce the burden of setting point estimates for standards and guidelines. The approach embodied in California's Proposition 65, largely written by EDF, sidesteps the entanglements of full risk assessment as the path to reaching decisions. Risk assessment is used to trigger disclosure provisions, rather than to specify control actions. Under Proposition 65, industries and other sources must disclose to the public when they release or otherwise expose people to chemicals known to cause cancer or reproductive toxicity in humans or animals. The requirement of disclosure is different from an overt, enforceable requirement to bring these exposures down to specific levels below which a defined increase in risk is estimated to occur. A recent review of implementation of Proposition 65 by California state government concluded that it is an efficient and productive mechanism for risk reduction (S.A. Book, testimony before the Senate Committee on Government Affairs, 27 March 1992). Several examples of product reformulation to avoid disclosure have already occurred.

A similar approach operates through the Toxics Release Inventory (TRI) in the United States, a program of data reporting and publication by EPA pursuant to the Superfund amendments. TRI requires industrial sources to report annually to EPA their releases of toxic chemicals into air, water, and land disposal. This reporting provision has elicited voluntary risk reduction measures in the absence of risk assessments on a chemical-by-chemical or release-by-release basis. Because of industry's positive reaction to disclosures, EPA has established the 33/50 initiative to reduce releases of high-priority toxic chemicals by 50% from 1990 to 1995 (*41*). The success of this program is due to two factors: the disclosure provisions of the TRI program are mandatory and accessible to computer-literate citizens, and most releases are generated by a small and identifiable segment of industry. About 10% of reporting facilities release more than 75% of the high-priority toxic chemicals (*41*). If the goal of halving these releases within 5 years can be accomplished without chemical- or process-specific regulations, then the need for quantitative risk assessments will be greatly reduced. It remains to be seen the extent to which such innovative approaches can be used in other arenas of risk reduction.

Conclusions. The rise of risk assessment in the United States in the late 1970s was supported and encouraged by many environmentalists. However, in practice, risk assessment has expedited regulatory actions to reduce risks, and public acceptance of the increasingly complex techniques of quantifying risk has diminished over the past decade. A review of the paralysis of EPA in regard to TCDD exemplifies the scientific and political problems with risk assessment. In addition, the exclusive focus of risk assessment on cancer has probably resulted in lost opportunities to reduce human exposure to other types of toxic substances and, by implication, the incidence of noncancer disease and disability.

Alternatives to risk assessment include a return to either technology-based or pure risk approaches, where quantification of risk is not necessary. The new Clean Air Act of 1990 to some extent exchanges the pure-risk approach for technology-based regulation, with more specific language to require development and application of advanced technology. Although no political consensus has yet been reached to repeal the remaining pure-risk provisions of the Food, Drug and Cosmetic Act as they affect pesticides and other food additives, it seems unlikely that extending the pure-risk strategy to other industrial chemicals would be politically acceptable. Portney (*7*) and others have discussed the political liabilities of promising "absolutist goals" in environmental policy.

Another alternative is the use of risk assessment as a semiquantitative signal for action, using disclosure to stimulate action without specifying the precise standard to be reached. This approach has in some cases resulted in relatively rapid response by industry to avoid disclosure, but the impact of information is ultimately limited in its efficacy to change human behavior (*42*). There may be cases where semivoluntary actions will not reduce risks to the level deemed acceptable. For instance, attempts to reduce smoking through education may have reached their plateau of efficacy in the United States. Nevertheless, this approach is preferable to handing over regulatory decision making to a technological elite, whose members alone can understand the increasingly arcane basis and data analysis of quantitative risk assessment (*15,16,33*). Environmentalists today, as in the past, accept the challenge of integrating public health goals into broader commitments to a just and workable democratic society.

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